



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the General Counsel


Office of the Chief Counsel
Food and Drug Administration
5600 Fishers Lane, GCF-1
Rockville, MD 20857

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MEMORANDUM

Date: June 04, 2004

To: Staff Attorneys and
Dockets Management Branch, Food and Drug Administration

From: Daniel E. Troy
Chief Counsel 

Subject: SEPARATION OF FUNCTIONS: Universal Reagents, Inc.;
Opportunity for a Hearing on a Proposal to Revoke U.S.
License No. 0887 (Docket No. 2003N-0232)

On July 10, 2003, the Center for Biologics Evaluation and Research published a notice of opportunity for a hearing, pursuant to 21 C.F.R. Part 12 (Formal Evidentiary Public Hearing), on the proposal to revoke the biologics license issued to Universal Reagents, Inc. for source plasma (68 FR 41162). Universal Reagents, Inc. requested a hearing on August 11, 2003.

Pursuant to 21 C.F.R. § 12.50(d) and 10.55(c), the Office of the Chief Counsel is required to invoke separation of functions for Part 12 hearings.

I am designating the following attorneys as advisors to the Commissioner of Food and Drugs and to the Center for Biologics Evaluation and Research:

Counsel for the Commissioner:

Daniel E. Troy
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